IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PENNSYLVANIA EMPLOYEE BENEFIT TRUST FUND, on behalf of itself and others similarly situated, Plaintiffs, v. ZENECA, INC. and ASTRAZENECA PHARMACEUTICALS, L.P., Defendants.	)	Civil Action No. 05-75 SLR

DEFENDANTS' OPENING BRIEF
IN SUPPORT OF THEIR MOTION TO DISMISS

Jack B. Blumenfeld (#1014)
R. Judson Scaggs, Jr. (#2676)
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 North Market Street
P. O. Box 1347
Wilmington, Delaware 19899
(302) 658-9200
Attorneys for Defendants

OF COUNSEL:

SIDLEY AUSTIN BROWN & WOOD LLP
Peter I. Ostroff
Mark E. Haddad
Alycia A. Degen
555 West Fifth Street
Los Angeles, CA 90013
(213) 896-6000

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Defendants AstraZeneca Pharmaceuticals LP and Zeneca, Inc. (collectively "AstraZeneca") respectfully submit this Brief in support of their Motion to Dismiss Plaintiff's Complaint, pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), for failure to state a claim upon which relief can be granted.

NATURE AND STAGE OF THE PROCEEDING

The Pennsylvania Employee Benefit Trust Fund ("Plaintiff") filed this putative nationwide class action on February 11, 2005, invoking the jurisdiction of this Court under 28 U.S.C. § 1332.

Plaintiff contends that AstraZeneca has defrauded the United States Food and Drug Administration ("FDA"), physicians and consumers through its promotion of the prescription drug, NEXIUM® (esomeprazole magnesium). Plaintiff seeks to represent a nationwide class of Nexium purchasers. Complaint ¶ 49. Plaintiff alleges five causes of action: (1) violation of the Delaware Consumer Fraud Act, 6 *Del. C.* § 2511 *et seq.*; (2) violations of the "Consumer Protection Statutes of the 50 States" (Complaint ¶ 65); (3) unjust enrichment; (4) common law fraud; and (5) negligent misrepresentation. Plaintiff seeks damages, injunctive relief, restitution, costs of suit and attorneys' fees.

SUMMARY OF ARGUMENT

1. Nexium is one of a class of drugs called proton-pump inhibitors (PPIs). The FDA has approved PPIs for the treatment of, among other conditions, erosive esophagitis (damage to the lining of the esophagus) and gastroesophageal reflux (or "acid reflux") disease, the symptoms of which include frequent heartburn. The pioneer drug in the class of PPIs was PRILOSEC® (omeprazole), which AstraZeneca also developed, patented, and marketed. Today, omeprazole is available in branded and

generic prescription formulas, and (for limited indications) in an over-the-counter formula ("Prilosec OTC"). *See* Complaint ¶¶ 2, 5.

2. Plaintiff alleges that AstraZeneca has deceived the FDA, physicians and consumers about the relative merits of Nexium and Prilosec. Plaintiff asserts that in order to obtain FDA approval, AstraZeneca conducted "deliberately skewed" studies that failed to compare "likely equivalent doses" of Prilosec and Nexium. *Id.* ¶¶ 6-7. For example, Plaintiff contends that, although a "study" showed that Nexium was "*slightly* more effective" than Prilosec at FDA-approved doses, other studies either did show or would have shown no difference between the two. *Id.* ¶¶ 7, 11, 27-28. On this basis, Plaintiff asserts that AstraZeneca's "massive" advertising campaign for Nexium, which allegedly makes "the claim of 'superiority'" for Nexium over Prilosec, is false and misleading. *Id.* ¶ 30, 33; *see also id.* ¶¶ 31-39.

3. Plaintiff's Complaint should be dismissed. The conduct that Plaintiff seeks to challenge is either protected by the First Amendment under the *Noerr-Pennington* doctrine, or is governed exclusively by federal law.

4. First, the First Amendment and *Noerr-Pennington* doctrine protect AstraZeneca's successful decision to petition the FDA to approve Nexium. Allegations that AstraZeneca fraudulently petitioned the FDA by, for example, submitting clinical studies that were improper in their selection of doses, cannot form the basis of any viable complaint. *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 139 (1961); *United Mine Workers of America v. Pennington*, 381 U.S. 657, 670 (1965); *see also, e.g., In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 359 n.3 (D. Mass. 2004).

5. Second, Plaintiff's claims are preempted. Congress has given the FDA exclusive jurisdiction over the field of new drug approval, including the determination of whether or not studies submitted in support of a new drug application are flawed and whether a given dose is appropriate. *See, e.g.,* 21 U.S.C. §§ 355(a), (b); 21 C.F.R. § 314.126; *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349, 353 (2001); *Healthpoint Ltd. v. Ethex, Corp.*, 273 F. Supp. 2d 817, 842 (W.D. Tex. 2001) (adequacy of safety and efficacy tests "are issues which are committed to the FDA").

6. Third, Congress and the FDA have determined that it is lawful and appropriate generally for pharmaceutical companies to promote prescription medicines through advertising directed at both patients and physicians. *E.g.,* 21 C.F.R. §§ 202.1, 203 *et seq.*; 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995). Plaintiff's broad attack on direct-to-consumer advertising and physician-directed promotion of prescription drugs therefore is similarly preempted. Plaintiff also may not use an unfocused lawsuit to silence an entire category of constitutionally protected commercial speech. *E.g., Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002).

7. Shorn of its attacks on the FDA's approval of Nexium, on the dosages that the FDA approved, on the studies on which that approval and the dosages are based, and on the practices of direct-to-consumer advertising and physician promotion, the Complaint contains only allegations of false advertising. These, too, are inadequate to state a claim. The Complaint attaches no ads, and appears to quote brief excerpts from only three alleged ads. *See* Complaint ¶¶ 5, 31. This does not remotely suffice to support Plaintiff's allegations of false advertising with the particularity required

under Fed. R. Civ. P. 9(b). Where, as here, false advertising is alleged without particularity, federal law requires that the complaint be dismissed.

8. Furthermore, the three advertising excerpts mentioned in the Complaint do not even contain the statements "as to the superior qualities of Nexium" (Complaint ¶ 30) that Plaintiff alleges were the cornerstone of the Nexium advertising campaign. Instead, these excerpts are fully consistent with the FDA's approval of an NDA for Nexium and with the FDA-approved Prescribing Information (label) for Nexium. *See id.* ¶¶ 5, 31 ("'the new purple pill'"; "'the purple pill called Nexium'"; and "'We've captured the essence of Prilosec and created a new PPI . . . introducing Nexium the powerful new PPI from the makers of Prilosec . . . .'"). Plaintiff's challenge to these statements is a collateral attack on the FDA's decision to approve Nexium and therefore is preempted by federal law. *E.g., Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 400 (5th Cir. 1999); *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 796-97 (2002).

9. At bottom, then, the Complaint effectively challenges the FDA's approval of a new drug. It contends either that the FDA was deceived into misapplying the law when it approved Nexium, or else that state law imposes additional standards that bar the marketing of FDA-approved drugs that are not markedly superior to existing drugs at "likely equivalent" doses. Allowing the Complaint to go forward would squarely conflict with the exclusive authority that Congress has granted the FDA over new drug approval. Such a complaint may not be litigated in any court; it must be directed, if anywhere, only to the FDA or to Congress.

10. The above reasons are more than sufficient grounds for dismissal of the Complaint. There are additional reasons, however, why each claim is defective as

a matter of state law. Plaintiff's claim under the Delaware Consumer Fraud Act ("DCFA") should be dismissed for the additional reason that the promotional conduct pleaded in this Complaint is protected under the DCFA's "safe harbor" provision. 6 *Del. C.* § 2513(b)(2). Plaintiff's DCFA claim also should be dismissed because Plaintiff has failed to allege facts to support the conclusion that it suffered injury *by means of* the allegedly false and misleading promotion alleged in the Complaint. *Stephenson v. Capano Devel.*, 462 A.2d 1069, 1077-78 (Del. 1983); *see Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 321 (5th Cir. 2002).

11. Plaintiff's "[a]lternative[]" claim for violation of the deceptive practices and consumer fraud acts of the fifty states (Complaint ¶ 65), should be dismissed for the additional reason that it is overinclusive and irrelevant. *See, e.g., Fitzgerald v. Chrysler Corp.*, 1996 WL 473456, at *7 (N.D. Ill. 1996), *aff'd* 116 F.3d 225 (7th Cir. 1997). Plaintiff's common law fraud, negligent misrepresentation, and unjust enrichment claims also should be dismissed because Plaintiff fails to allege justifiable reliance or causation. *See Stephenson*, 462 A.2d at 1074; *Outdoor Technologies, Inc. v. Allfirst Financial, Inc.*, 2001 WL 541472, at * 5 (Del. Super. Ct. April 12, 2001).

STATEMENT OF FACTS

Plaintiff contends that AstraZeneca "launched a multi-prong attack" in an effort to switch consumers from Prilosec to Nexium before AstraZeneca faced competition for Prilosec from generic forms of omeprazole. Complaint ¶¶ 4-5. Plaintiff alleges that AstraZeneca "attacked generic manufacturers in court, seeking to delay entry of competition," *id.* ¶ 4, then "obtained FDA approval for" the "newly patented" Nexium, *id.* ¶ 5, notwithstanding alleged fraudulent concealment of the "true facts" about Nexium from the FDA, *id.* ¶ 46.

Specifically, Plaintiff alleges that the clinical studies submitted to the FDA in support of Nexium were flawed because they "compared twice the dose of Nexium to the standard dose of Prilosec." *Id.* ¶ 11. "With the studies deliberately skewed, Nexium looked like an improvement – but still only marginally so and in just two of the four trials." *Id.* ¶ 7. In Plaintiff's judgment, a "dose of 40 mg [of Nexium] is not needed in most patients and a fair comparison of 20 mg of Nexium to 20 mg of Prilosec would not have proven Nexium to be superior." *Id.* ¶ 11.

Plaintiff also alleges that AstraZeneca concealed "the difference between the formula for Nexium and the formula for Prilosec," *id.* ¶ 59, and "did not publish" studies of "likely equivalent doses" that allegedly either did show or would have shown no difference between the two drugs. *Id.* ¶¶ 7, 28. Plaintiff quotes a former federal official's statement that "[t]he fact is, Nexium is Prilosec . . . [i]t is the same drug." *Id.* ¶¶ 12, 42.

Plaintiff alleges that AstraZeneca then conducted a "massive advertising campaign" to promote Nexium. *Id.* ¶ 5. Plaintiff attacks the merits of direct-to-consumer advertisement of prescription drugs in general, complaining that "[s]tudies show that such advertisements are effective in causing patients to pressure doctors into prescribing expensive and marginally helpful new drugs." *Id.* ¶ 34; *see also* ¶¶ 35-36, 60(b). Plaintiff also attacks physician-directed promotion, such as the practice of "sampling" – providing free drug samples to physicians. *Id.* ¶¶ 5, 32, 60(e).

Finally, plaintiff contends that AstraZeneca falsely promoted Nexium to physicians and consumers as "superior" to Prilosec. *Id.* ¶¶ 5, 11, 30-33, 59, 60. Plaintiff quotes one excerpt from AstraZeneca's 2000 Annual Report regarding Nexium's

"'significant clinical improvements'" and "'more effective acid inhibition'" over Prilosec, and claims that AstraZeneca used "themes" from this report in its advertising. *Id.* ¶¶ 29-30; *see also id.* ¶ 8. Plaintiff does not attach any ad to the Complaint, however, or purport even to quote any ad in full. The only excerpts Plaintiff offers from any ad allegedly directed at consumers state: "the new purple pill" and "the purple pill called Nexium." *Id.* ¶ 5.

The only excerpt of a physician-directed ad that Plaintiff offers is the following: "'We've captured the essence of Prilosec and created a new PPI . . . introducing Nexium the powerful new PPI from the makers of Prilosec . . . .'" *Id.* ¶ 31. Other than that, plaintiff offers only a *Wall Street Journal* reporter's account of "one type of pitch made to doctors" in "Manhattan," in which the AstraZeneca representative allegedly failed to say that "at equivalent doses, Nexium was not more effective, nor was the claim of 'superiority' accurate in that the clinical study showed a slight increase in efficacy for only one type of patient." *Id.* ¶¶ 32-33.

Nowhere does Plaintiff allege that any of these ads were directed at Plaintiff or at third-party payors generally. Nowhere does Plaintiff allege that anyone affiliated with Plaintiff actually viewed the Nexium ads that Plaintiff challenges, or received the "pitch" described in the *Wall Street Journal*. Plaintiff alleges that AstraZeneca "gave discounts to managed care plans and hospitals," *id.* ¶ 5, but Plaintiff does not allege that it was offered or received any such discount. Plaintiff alleges only that it is a labor-management trust fund that provides healthcare benefits and that it "paid, in Delaware and elsewhere, for some or all of the purchase price of Nexium prescribed to one or more of its participants or beneficiaries." *Id.* ¶ 13. In sum, Plaintiff attacks

AstraZeneca for having successfully promoted the use of its new PPI, Nexium, rather than its old PPI, Prilosec.

ARGUMENT

A complaint should be dismissed under Federal Rule of Civil Procedure 12(b)(6) where, "even accepting the allegations in the complaint as true and drawing every reasonable inference in favor of the plaintiffs, they have failed to adequately plead . . . [a] cause of action." *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004); *see also* Fed. R. Civ. P. 12(b)(6). "But a court need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." *Morse v. Lower Merion School Dist.*, 132 F.3d 902, 906, 906 n.8 (3d Cir. 1997) (quoting *In re Burlington Coat Factory Securities Litigation*, 114 F.3d 1410, 1429-30 (3d Cir. 1997)).

This Complaint should be dismissed for two independent reasons. First, federal law protects the conduct challenged here and preempts state law challenges to it. Second, each claim is independently defective under state law.

I. FEDERAL LAW BARS AND PREEMPTS PLAINTIFF'S COMPLAINT.

Plaintiff alleges that AstraZeneca has misled the FDA, patients, and doctors, as to the relative merits of Nexium and Prilosec. The Complaint rests on three basic allegations: (a) that AstraZeneca obtained FDA-approval for a 40 mg dose of Nexium by conducting "deliberately skewed" studies that failed to compare "likely equivalent doses" of Nexium and Prilosec (Complaint ¶¶ 5-7, 11-12, 27-28, 39-42, 46); (b) that AstraZeneca then engaged in a massive advertising campaign to promote Nexium; and (c) that AstraZeneca's ads misleadingly claim that Nexium is superior to Prilosec.

The first two allegations cannot support any state law claim as a matter of law: Plaintiff may not litigate the validity of the studies that supported the approval of Nexium, the dosages that the FDA approved, or the legitimacy of direct-to-consumer advertising or promotions to physicians. Although in theory a plaintiff may litigate whether a particular advertisement is false and misleading, this Plaintiff has put no such advertisement at issue here. The Complaint therefore fails to state any claim.

A. Plaintiff's Challenge To The Studies And Dosages Of Nexium Is Barred And Preempted.

First, AstraZeneca's conduct in petitioning the FDA for approval of Nexium – including seeking and obtaining approval for a 40 mg dose of Nexium, and designing clinical studies to support that request – is constitutionally protected and immune from state law challenge under the *Noerr-Pennington* doctrine. *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 139 (1961); *United Mine Workers of America v. Pennington*, 381 U.S. 657, 670 (1965); *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 359 n.3 (D. Mass. 2004) (*Noerr* protects petitioning the FDA); *In re Tamoxifen Citrate Antitrust Litig.*, 277 F. Supp. 2d 121, 135 (E.D.N.Y. 2003) (*Noerr* protects petition to the FDA for a stay of approval of new generic drugs); *see also In re Warfarin Sodium Antritrust Litig.*, 1998 WL 883469, at *6-8 (D. Del. Dec. 7, 1998), *rev'd on other grounds*, 214 F.3d 395 (3d Cir. 2000). Although *Noerr-Pennington* does not protect conduct amounting to a sham, the Complaint concedes that AstraZeneca succeeded in obtaining FDA approval (Complaint ¶ 5), and so the petitioning here was not a "sham" as a matter of law. *Professional Real Estate Investors,*

Inc. v. Columbia Pictures, Inc., 508 U.S. 49, 61 (1993); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 n.5 (Fed. Cir. 1998).[1]

Second, apart from *Noerr-Pennington*, the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), and the FDA's implementing regulations preempt any state law challenge to the FDA's approval of Nexium, to the studies on which that approval is based, or to the dosages that the FDA approved. Under the Supremacy Clause, U.S. Const., art. VI, cl. 2, state laws that interfere with or are contrary to federal law are preempted. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000). In particular, state law may be "impliedly" preempted where "Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby 'left no room for the States to supplement' federal law." *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 699 (1984) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). State law is preempted also to the extent that it "conflicts with federal law or 'stands as an obstacle to the accomplishment and execution of the full purposes of objectives of Congress.'" *Lawrence County v. Lead-Deadwood School Dist. No. 40-1*, 469 U.S. 256, 260 (1985) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984)); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525-26 (1977) (quoting *Hines v.*

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[1] Plaintiff's attack upon AstraZeneca's litigation against generic manufacturers likewise is barred under *Noerr-Pennington*. *See* Complaint ¶ 4 (alleging that AstraZeneca "attacked generic manufacturers in court, seeking to delay entry of competition," as part of its "multi-prong attack"); *see also Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972) (*Noerr* protects "litigation"); *Nobelpharma*, 141 F.3d at 1071 (Noerr is applicable to patent litigation). Indeed, one federal court has already held that much of the Prilosec-related conduct challenged here is protected conduct. *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 224 (S.D.N.Y. 2002). Accordingly, these allegations may not support any claim for relief.

Davidowitz, 312 U.S. 52, 67 (1941)). As shown below, Congress has occupied the field of new drug approval, including determining whether particular studies support the approval of a new drug or whether a particular dose of that drug is appropriate; in addition, Plaintiff's claims conflict with federal law and frustrate the achievement of the "full purposes and objectives of Congress." *Hines*, 312 U.S. at 67.

In *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349, 353 (2000), the Supreme Court held that the FDCA preempts a claim that, but for the defendant's fraud on the FDA, the FDA would not have approved the medical device that allegedly injured plaintiffs. The same principle applies to Plaintiff's allegation here that AstraZeneca "knowingly, willfully and fraudulently concealed the true facts about Nexium" during "the proceedings before the FDA" by such means as failing to disclose the difference between the formulas for Nexium and Prilosec, failing to publish certain studies, or conducting "deliberately skewed" studies of improper dosages to support FDA approval of a 40 mg dose of Nexium. *See* Complaint ¶¶ 6-7, 11-12, 27-28, 42, 46.

The approval of a new drug, the adequacy of supporting studies, and the appropriate dosages, are all issues that Congress has committed exclusively to the FDA, and may not be litigated under state law. The FDA has exclusive jurisdiction to determine whether to approve a "new drug application" ("NDA") to market a drug in the United States. 21 U.S.C. §§ 355(a), (b). The FDA requires applicants to include in the NDA a "full description of the drug substance and its chemical properties," and the product label that is submitted with the NDA (and later accompanies the drug itself) must disclose the "chemical name and formula of the drug." 21 C.F.R. §§ 201.57(a)(vi), 314.50(d)(l)(i); *see also* 21 U.S.C. § 355(b)(1)(C). To support an NDA, the FDA

requires applicants to submit clinical studies that are "adequate and well-controlled." *See* 21 C.F.R. § 314.126. The FDA will deny an NDA if it determines that there "is a lack of substantial evidence consisting of adequate and well-controlled investigations . . . that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling." 21 C.F.R. § 314.125(b)(5). The FDA's approval of an NDA thus reflects, among other things, a determination that the clinical studies upon which the approval is based are adequate and well-controlled and that the drug formula was properly disclosed. *See Healthpoint Ltd. v. Ethex, Corp.*, 273 F. Supp. 2d 817, 842 (W.D. Tex. 2001) (whether the plaintiff's tests of its product were sufficient to show safety and efficacy "are issues which are committed to the FDA").

The FDA's decision to approve Nexium also preempts Plaintiff's contention that it is inherently misleading for AstraZeneca to base a marketing campaign on the advantages of a 40 mg dose of Nexium. *See* Complaint ¶¶ 6-8, 11-12, 27-28, 32-33, 39-42, 53, 59-60. For example, Plaintiff contends that one study of Nexium 40 mg that was submitted to the FDA showed that Nexium was "*slightly* more effective" than Prilosec at the FDA-approved doses (Complaint ¶ 27 (emphasis in original); *see also id.* ¶¶ 6-7 (Nexium "marginally" an "improvement" in "two of the four trials")), but contends that studies at likely equivalent doses would have shown no differences, and therefore marketing the benefit of Nexium at the FDA-approved 40 mg dose is misleading. Complaint ¶¶ 6-8, 11-12, 27-28, 32-33, 39-42, 53, 59-60. The selection of approved doses, however, is part of the FDA's decision to approve an NDA. An NDA must include "substantial evidence" consisting of "adequate and well-controlled studies"

to support, among other things, "the dosage and dose interval recommended" in the approved product labeling. 21 C.F.R. §§ 314.50(d)(5)(v), 315.125(b)(5); *see also* 21 C.F.R. § 312.21 (requiring Phase 1 clinical studies to address, among other things, "the side effects associated with increasing doses"); 21 C.F.R. § 314.126(b)(2)(ii) (describing requirements for a dose-comparison study to be considered adequate and well-controlled). The FDA-approved labeling also must provide information on the recommended dose for each indication. *See* 21 C.F.R. §§ 201.57(a)(ii), (j), 201.100(b)(2). Like the FDA's decision to approve Nexium generally, the FDA's decision to approve a 40 mg dose of Nexium for marketing in the United States is not subject to collateral attack.

Finally, Congress has preempted the use of state law to enforce the new drug approval requirements of the FDCA. Instead, Congress gave the FDA the power and discretion to enforce the requirements of the FDCA. 21 U.S.C. § 371(a); *id.* § 337(a) ("all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States"); *id.* § 336 (FDA need not prosecute "minor violations of [the FDCA] whenever [the FDA] believes that the public interest will be adequately served by a suitable written notice or warning"). The FDA has exercised this authority by asserting "primary jurisdiction" over all "issues within its statutory mandate," both as to the initial determination of the issue and any decision that the agency determines "should be reconsidered." 21 C.F.R. § 10.25(b). Congress also did not create a private right of action under federal law to enforce the provisions of the FDCA. *See* 21 U.S.C. §§ 337(a), 371(a). If Plaintiff wishes to contend that AstraZeneca deceived the FDA through the design or presentation of its studies, then its sole remedy is

to petition the FDA. *See* 21 C.F.R. §§ 10.25-10.45; *see also Buckman*, 531 U.S. at 349; *cf. Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (rejecting a Lanham Act claim that rested on the contention that the defendant's product was not properly on the market).

Thus, in the FDCA, Congress has occupied the field of new drug approval, including the evaluation of supporting studies and the setting of appropriate dosages. Furthermore, any attempt to litigate under state law whether the FDA's approval of a 40 mg dose of Nexium was appropriate, whether the studies that supported that approval were "skewed," or whether Nexium at 40 mg (or at any dosage) ever should have been approved at all, would conflict with the FDA's resolution of these issues and would frustrate the purposes of the FDCA. For these reasons, to the extent that the Complaint challenges the studies that support the FDA's approval of, or the marketing of, a 40 mg (or other) dose of Nexium, the Complaint is preempted.

B. Plaintiff's Challenge to Direct-to-Consumer and Physician Advertising Practices Also Is Barred And Preempted.

Plaintiff broadly challenges direct-to-consumer advertising per se, claiming that it "caus[es] patients to pressure doctors into prescribing expensive and marginally helpful new drugs," notwithstanding the doctor's professional obligation to make an independent medical judgment as to whether or not to prescribe a drug. Complaint ¶ 34. Plaintiff also challenges physician-directed promotion per se, such as providing free samples. *See id.* ¶¶ 5, 30, 32, 60(e). This is commercial speech that also is protected from state law challenge under both the First Amendment and the Supremacy Clause.

The First Amendment protects commercial speech that is neither false nor misleading. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). Plaintiff may not use an unfocused lawsuit to silence an entire category of constitutionally protected commercial speech. See *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 374 (2002) ("Even if the Government had argued that the . . . speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions."); *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 60, 61, 66, 73 (D.D.C. 1998) (recognizing the Supreme Court's "preference for combating potentially problematic speech with more speech" and holding that restrictions on the distribution of materials regarding off-label use of prescription drugs violated the First Amendment), vacated in part on other grounds, 202 F.3d 331 (D.C. Cir. 2000). As a result, absent a viable, particularized allegation of falsehood, Plaintiff may not challenge AstraZeneca's marketing of an FDA-approved drug.

In addition, Plaintiff's broad challenge to direct-to-consumer advertising is preempted by the FDA's decision to permit such advertising. *See, e.g.*, 21 C.F.R. § 202.1; *Geier*, 529 U.S. at 872, 875; *Lawrence County*, 469 U.S. at 260-61. Congress has granted the FDA authority to regulate the marketing of and promotional materials for approved drugs (21 U.S.C. § 352(n); *see also id.* §§ 321(n), 331(a), 352(a), 353(c), (d)), and the Federal Trade Commission ("FTC") agrees that the FDA should exercise primary responsibility for regulating advertising of prescription drugs. *Working Agreement*

Between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1971). Since 1985, the FDA has permitted drug manufacturers to promote prescription drugs not only to physicians but also to consumers, subject to compliance with detailed regulations. *See* 21 C.F.R. § 202.1; *see generally* Inter-Agency Group on Advertising and Promotion, Food and Drug Administration, Guidance for Industry: Consumer-Directed Broadcast Advertisements (1999), available at http://www.fda.gov/cder/guidance/1804fnl.htm (last visited March 30, 2005); 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995) (discussing history of DTC advertising).

Plaintiff therefore may not invoke state law to challenge direct-to-consumer advertising per se, or the promotion of prescription drugs to physicians per se. Any such use of state law would directly conflict with federal law, which permits such marketing. *See* 21 U.S.C. § 352(n); 21 C.F.R. §§ 202.1, 203 *et seq.*; *Lawrence County*, 469 U.S. at 260-61. If Plaintiff disagrees with the FDA's decision to permit direct-to-consumer advertising or thinks additional regulation is needed, it may petition the FDA for a new rule. *See* 21 C.F.R. § 10.25 ("An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action."); *id.* §§ 10.30-45 (setting forth procedures for a citizen petition to the FDA). It may not mount a collateral attack.

C. Plaintiff Fails To Plead A Viable Claim Of False Advertising.

Plaintiff's remaining allegations concern allegedly false advertising. In theory, a plaintiff may state a claim for false advertising of a prescription drug that is not preempted. But to state a viable claim, Plaintiff must plead its claim of false advertising with the particularity required by Federal Rule of Civil Procedure 9(b), and must do so

with respect to ads that support Plaintiff's theory of falsity. Plaintiff has done neither here.

1. Plaintiff Fails to Plead with the Particularity Required under Federal Rule of Civil Procedure 9(b).

In a case premised on an alleged fraudulent scheme, it is not sufficient to allege the fraudulent act using broad, general characterizations.[2] Under Federal Rule of Civil Procedure 9(b), "[i]n all averments of fraud or mistake, the circumstances constituting the fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). The particularity requirement applies with special force where, as here, a complaint challenges commercial speech. *See Central Hudson Gas & Elec. Corp.*, 447 U.S. at 566; *Peel v. Attorney Registration and Disciplinary Comm'n of Ill.*, 496 U.S. 91, 100 (1990) (explaining that although a state may prohibit misleading advertising, the state "'may not place an absolute prohibition'" on advertising that is only potentially misleading, if the information also may be presented in a way that is not deceptive) (*quoting In re R. M. J.*, 455 U.S. 191, 203 (1982)).

To satisfy Rule 9(b), the complaint must set forth with sufficient particularity the circumstances of the alleged fraud "'in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard

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[2] Plaintiff's Complaint is replete with allegations of fraud and expressly asserts a claim for common law fraud based on those same allegations. Complaint ¶¶ 71-76. For example, the Complaint alleges that AstraZeneca "plotted" a "fraudulent and/or deceptive scheme," including making "false" statements about Nexium, "knowingly, willfully and fraudulently conceal[ing] the true facts about Nexium," submitting "deliberately skewed" studies, and "omit[ting] material information known to [AstraZeneca] that would have disclosed materially adverse facts to doctors and consumers in order to induce doctors to prescribe Nexium and consumers to purchase Nexium." Complaint ¶¶ 7, 12, 25, 46, 53, 60(a), 60(c).

defendants against spurious charges of immoral and fraudulent behavior.'" *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004) (*quoting Seville Indus. Mach. Corp. v. Southwest Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)). A plaintiff "may satisfy this requirement by pleading the 'date, place or time' of the fraud, or through 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" *Lum*, 361 F.3d at 224 (quoting *Seville Indus. Mach. Corp.*, 742 F.2d at 791)). "Plaintiffs also must allege who made a misrepresentation to whom and the general content of the misrepresentation." *Id.* The requirements of Rule 9(b) "apply to all cases where the gravamen of the claim is fraud even though the theory supporting the claim is not technically termed fraud." *Toner v. Allstate Ins. Co.*, 821 F. Supp. 276, 283, 285 (D. Del. 1993) (dismissing unjust enrichment claim based on fraud for failure to satisfy Rule 9(b)); *Hough/Loew Assoc., Inc. v. CLX Realty Co.*, 760 F. Supp. 1141, 1145, *vacated in other part*, 1991 WL 86937 (E.D. Pa. 1991) (reviewing the sufficiency of a negligent misrepresentation claim under Rule 9(b)); *see also Lum*, 361 F.3d at 220 (explaining that "fraud must be pled with particularity in *all* claims based on fraud" and dismissing for failure to satisfy Rule 9(b) an antitrust claim that was based on an alleged fraudulent scheme).

The Complaint fails to attach a single allegedly false advertisement. It contains just three quotes that purport to be excerpts from Nexium advertisements, but fails to allege the complete content or context of any of them, let alone the date, place, or medium of publication, or who affiliated with the Plaintiff saw them. Complaint ¶¶ 5, 31. Without this information, it is impossible to tell whether the advertisements were print or broadcast, when or where they ran, whether they contained additional language not

quoted, in what context the excerpted language appeared, or whether the quotes are even from advertisements. Absent any context or details, the excerpts do not begin to meet the pleading requirements of Rule 9(b). *Compare Seville Indus. Mach. Corp.*, 742 F.2d at 791 (finding allegations of fraud sufficient where the plaintiff "inject[ed] precision and some measure of substantiation into their allegations of fraud" by "incorporating into the complaint a list identifying with great specificity the pieces of machinery that were the subject of the alleged fraud," identifying which pieces were the subject of which allegedly fraudulent transaction, and setting forth the nature and subject of each alleged misrepresentation).

For example, the failure to plead with specificity precludes any determination whether the proffered excerpts were published within the applicable three-year limitations period. *See, e.g.*, *Pender v. DaimlerChrysler Corp.*, 2004 WL 2191030, at * 2 (Del. Super. Ct. July 30, 2004) (three-year statute of limitations applies to DCFA claims);[3] *Lum*, 361 F.3d at 225 (finding claim not pled with particularity where the plaintiffs did not indicate the date, time, or place of the alleged misrepresentations, the transactions in connection with which the misrepresentations were made, or who made the misrepresentations to whom). Such a timeline is particularly important here, because Plaintiff alleges that soon after the initial marketing campaign in 2001, AstraZeneca "dropped all references to the older drug [Prilosec] in its advertisements." Complaint ¶ 5.

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[3] The same three-year statute of limitations governs each of Plaintiff's claims. *See* 10 *Del. C.* § 8106; *Solow v. Aspect Resources, LLC*, 2004 WL 2694916, at *3 (Del. Ch. Oct. 19, 2004) (fraud); *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 2004 WL 405913, at *5, n. 45 (Del. Ch. Mar. 2, 2004) (unjust enrichment); *Advocat v. Nexus Indus., Inc.*, 497 F. Supp. 328, 334 (D. Del. 1980) (negligent misrepresentation).

Plaintiff's omission of any actual advertisements is especially telling given that the Complaint alleges that AstraZeneca spent "massive" amounts of money to promote Nexium, including "in the first ten months of 2001 alone, . . . $98 million on direct-to-consumer promotions" (Complaint ¶¶ 5, 30), and cites to other materials that are not advertisements for Nexium, most of which were not even published by AstraZeneca. *See, e.g., id.* ¶¶ 32, 39-41 (quoting articles from the *Wall Street Journal*, the *Los Angeles Times*, *Health Facts*, and *Managed Healthcare Executive*). The only alleged AstraZeneca-published document identified in the Complaint, AstraZeneca's 2000 Annual Report, was not directed at consumers, was not an advertisement at all, and was issued well outside the three-year statute of limitations. *Id.* ¶¶ 8, 29-30. Although the Complaint alleges that the Annual Report illustrates "themes" that appeared in Nexium advertising, it fails to attach or quote ads to support that claim. In sum, the Complaint lacks allegations of false advertising that are stated with the particularity required under Rule 9(b). Plaintiff's Complaint therefore should be dismissed.

2. Plaintiff Has Not Alleged False or Misleading Advertising.

Although the arguments above suffice to show that the Complaint should be dismissed, a further deficiency in the pleading is important to note. None of the advertising excerpts contains the comparative statements of superiority that Plaintiff claims are false or misleading. *See* Complaint ¶¶ 30, 60(a).

The first excerpt merely states, "the purple pill"; the second states "the purple pill called Nexium." *Id.* ¶ 5. Plaintiff identifies no respect in which these excerpts make any claim of superiority over Prilosec.

The third alleged advertising excerpt states: "We've captured the essence of Prilosec and created a new PPI . . . introducing Nexium, the powerful new PPI from the makers of Prilosec." *Id.* at ¶ 31. Again, the excerpt contains no claim of superiority. The statement that AstraZeneca "captured the essence of Prilosec" is consistent with the Complaint's allegation that Nexium and Prilosec are related compounds. *Id.* ¶¶ 12, 39-42. The statement that Nexium is "new" cannot support a false advertising claim: the FDA approved the "new drug application" for Nexium (*Id.* ¶ 5; *see also* 21 U.S.C. § 355(b)), which affords the sponsor six months from the date of launching the product in which to advertise its product as "new." *See* FDA Division of Drug Marketing, Advertising, and Communications Frequently Asked Questions, available at http://www.fda.gov/cder/ddmac/FAQS.HTM#new (last visited March 29, 2005); 3 Trade Reg. Rep. (CCH) ¶ 7765 n.20 (citing Federal Trade Commission Advisory Opinion #120). Finally, the description of Nexium as "powerful" does not compare Nexium with Prilosec, is fully consistent with the FDA's approval of Nexium as safe and effective for the indications on its labeling (Complaint ¶ 5; 21 U.S.C. § 355(b), (d)) and is not an actionable description as a matter of law. *See Coca-Cola Co. v. Nehi Corp.*, 36 A.2d 156, 165-66 (Del. 1944) (holding that common laudatory adjectives, such as "delicious" and "refreshing" are not actionable statements); *Solow v. Aspect Resources, LLC*, 2004 WL 2694916, at *3 (Del. Ch. Oct. 19, 2004) (holding that statement that company had "skills, experience, and resources" could not serve as basis for a fraud claim); *Smirniotis v. Smith Volkswagen Ltd.*, 2000 WL 33653433, at *4 (Del. Com. Pl. July 20, 2000) (holding that statement that car was "in excellent condition" was not an actionable statement); *see also Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d. 296, 300-01 (S.D.N.Y. 1998)

(holding that subjective claims of product superiority regarding medical testing product were nonactionable).

Plaintiff thus has failed to allege any false or misleading advertisements. The excerpts are consistent with the FDA's approval of an NDA for Nexium and with the FDA-approved Prescribing Information (label) for Nexium. Because Congress has given the FDA exclusive authority to approve new drugs, 21 U.S.C. § 331, 352, 355, 371(a), the FDA approved Nexium, and it is lawful and appropriate for AstraZeneca to have marketed Nexium as it has. Plaintiff's false advertising claims with respect to these excerpts are preempted by federal law. *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 400 (5th Cir. 1999); *see Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 796-97 (2002) (holding that challenge to advertisement that repeated information in FDA-approved label was preempted by federal law); *cf. Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 662-63 (7th Cir. 1997) (EPA-approved label); *Taylor AG Indus. v. Pure Gro*, 54 F.3d 555, 561 (9th Cir. 1995) (same).

II. EACH OF PLAINTIFF'S CLAIMS IS INDEPENDENTLY DEFECTIVE UNDER STATE LAW

A. Plaintiff Fails to State a DCFA Claim.

The Delaware Consumer Fraud Act ("DCFA") prohibits "deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise." 6 *Del. C.* § 2513(a). While enforceable by the Delaware Attorney General (6 *Del. C.* § 2522), the DCFA also permits a private plaintiff to recover damages "which are a direct and proximate result of the false advertising." *Stephenson v. Capano*

Devel., 462 A.2d 1069, 1077-78 (Del. 1983); *see also* 6 *Del. C.* § 2525. For two reasons in addition to those in Part I, the Complaint fails to state a DCFA claim.

1. Plaintiff's DCFA Claim Falls Within the DCFA Exclusionary Provision.

Plaintiff's DCFA claim should be dismissed because the promotional conduct pleaded in this Complaint is protected under the DCFA's exclusion for "any advertisement or merchandising practice which is subject to and complies with the rules and regulations, of and the statutes administered by, the Federal Trade Commission" ("FTC"). 6 *Del. C.* § 2513(b)(2).

The FTC enforces Section 5 of the Federal Trade Commission Act ("FTC Act"), which broadly prohibits "deceptive or unfair acts or practices in or affecting commerce." 15 U.S.C. § 45. Section 12 of the FTC Act further prohibits the dissemination of false advertisements for food, drugs, devices, services or cosmetics. 15 U.S.C. § 52. The FDCA also gives the FDA authority to regulate drug advertising. 21 U.S.C. § 352(n); *see also* 21 U.S.C. §§ 321(n), 331(a), 353(c), (d). The FTC has determined that in the area of prescription drugs, the FDA, and not the FTC, should exercise primary responsibility for regulating advertising. *Working Agreement Between FTC and Food and Drug Administration*, 4 Trade Reg. Rep. (CCH) ¶ 9851 (1971). The FTC thus has recognized the need for specialized regulation of prescription drug advertising and has deferred to the FDA's expertise in the area of prescription drugs. Accordingly, for purposes of the DCFA exclusion in the case of prescription drugs, the Court must look to FDA rules and regulations. Because the challenged advertising excerpts do not contain the alleged false statements and say nothing more than what the FDA permits AstraZeneca to advertise, Plaintiff's claims are precluded under the DCFA.

The FDA permits pharmaceutical companies to engage in commercial speech, including promoting their drugs directly to consumers, as well as to physicians (by providing them with free samples, as well as by other means), so long as that promotion is fair and balanced and consistent with the product's FDA-approved label.[4] *See, e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 202.1 (detailed regulations governing advertising of prescription drugs); *see also* Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293; 21 U.S.C. §§ 321(n), 331(a), 353(c), (d); 21 C.F.R. § 203 *et seq.*; Inter-Agency Group on Advertising and Promotion, Food and Drug Administration, Guidance for Industry: Consumer-Directed Broadcast Advertisements (1999), available at http://www.fda.gov/cder/guidance/1804fnl.htm (last visited March 30, 2005); *see generally* 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995) (discussing history of DTC advertising).

Nothing in the advertising excerpts quoted in the Complaint or the general promotional activity is inconsistent with the FDA's approval of Nexium or the FDA-approved label for Nexium.[5] Notably, the FDA specifically allows companies to advertise their newly approved products as "new" for six months from the date of launch following FDA approval; the FTC follows a similar rule. *See* FDA Division of Drug

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[4] The label is an integral part of the new drug application, 21 U.S.C. §§ 352, 355(b)-(e); 21 C.F.R. § 312.105, 314.125; and the drug may not be approved if the label is "false or misleading in any particular." § 314.125(b)(6). The label must be approved by the FDA, 21 U.S.C. §§ 352, 355(b)-(e); 21 C.F.R. § 312.105, 314.125, cannot be altered without FDA approval, 21 C.F.R. § 314.70; see also 21 U.S.C. §§ 352, 355, and must accompany the drug product, 21 U.S.C. § 352.

[5] The approved label for Nexium is publicly available at the FDA's website, http://www.fda.gov/cder/foi/nda/2001/21154_Nexium_prntlbl.pdf. *See* note 5, *supra*.

Marketing, Advertising, and Communications Frequently Asked Questions, available at http://www.fda.gov/cder/ddmac/FAQS.HTM#new (last visited March 29, 2005); 3 Trade Reg. Rep. (CCH) ¶ 7765 n.20 (citing Federal Trade Commission Advisory Opinion #120). AstraZeneca's challenged advertising and promotional activity is thus specifically permitted under FDA and FTC rules and is insufficient to state a viable claim under the DCFA. The Complaint contains no allegations of conduct that would fall outside the exclusionary provision. Plaintiff's DCFA claim therefore should be dismissed.

2. Plaintiff Fails to Allege Causation.

Plaintiff's DCFA claim should be dismissed for the additional reason that Plaintiff has failed to allege that it suffered injury *by means of* AstraZeneca's alleged misconduct.[6] To recover damages on its DCFA claim, Plaintiff must establish that the alleged DCFA violation caused Plaintiff's alleged injury. *Stephenson*, 462 A.2d at 1077-78 (DCFA plaintiff may recover damages "which are a direct and proximate result of the false advertising").

Conspicuously absent from this Complaint are any factual allegations that support the conclusion that Plaintiff was injured as a result of the allegedly false and misleading promotion alleged in the Complaint. Plaintiff alleges that it "has paid . . . for

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[6] *See* 6 *Del. C.* § 2525(b) (declaring "any claim against any person who has acquired any money or property, real or personal, by means of any acts or practices declared by this subchapter to be unlawful"); 6 *Del. C.* § 2524(c) (allowing "[a]ny person who has suffered damages as a result of the use or employment of any such unlawful acts or practices" to participate with general creditors to recover out-of-pocket losses after a receiver has been appointed); *Stephenson*, 562 A.2d at 1077 ("A plaintiff, therefore, may recover for any injury resulting from the direct and natural consequences of his acting on the strength of the defendant's statements. . . A similar principle applies in actions under the [DCFA].").

some or all of the purchase price of Nexium prescribed to one or more of its participants or beneficiaries" and that the payments "were substantially more than payments would have been for generic versions of Prilosec." Complaint ¶¶ 13, 62; *see also id.* ¶ 66 ("Plaintiff and the Class have suffered actual economic damage by paying for Nexium instead of the equally efficacious generic version of Prilosec").

The Complaint, however, fails to identify anyone affiliated with Plaintiff who was exposed to any ads, or any decision that such person would have made differently if he or she had not seen them that, in turn, caused injury to Plaintiff. Plaintiff does not allege that absent any misrepresentations, it would have taken steps so as not to purchase Nexium, or to purchase it at a lesser price.

Plaintiff's Complaint does not contain any theory of causation that would overcome the barrier the learned intermediary doctrine presents to proof of causation. *See Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 321 (5th Cir. 2002) (concluding that the plaintiffs failed to plead facts essential to causation on their economic loss claims because before a patient could take the drug, a physician had to make an independent medical judgment to prescribe it); *see also Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399-400 (Del. 1989) (adopting learned intermediary doctrine in Delaware).[7] Plaintiff must prove that AstraZeneca's allegedly deceptive conduct – which Plaintiff has not yet

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[7] *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 349-50 (2d Cir. 2003), is not to the contrary, because it, too, required allegations of causation. *See id.* at 349 n.9. There, Judge Calabresi offered a hypothetical to illustrate why a third-party payor could state a claim of direct injury from a fraudulent scheme to market a drug that was the same as an existing drug. *Id.* at 350. Such a scheme was not alleged in that case, however, and so the court had no occasion to address the issues of fraud-on-the-FDA and preemption that make the hypothetical incomplete and inapposite here. Also, the plaintiffs in *Desiano* did allege causation in a manner entirely absent here. *See id.* at 349 n.9.

identified – was the proximate cause of Plaintiff's injury. *Stephenson*, 462 A.2d at 1077. But on the facts alleged in the Complaint, under the learned intermediary doctrine, it is the prescribing physician who makes "the critical choice" about whether to prescribe Nexium, or Prilosec, or generic omeprazole, or some other brand of PPI to a given patient. *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 256 (D. Del. 2002), *aff'd* 391 F.3d 516 (3d Cir. 2004). The Complaint contains no factual allegations that, if proven, would show that but for AstraZeneca's false or misleading advertising, one or more physicians who prescribed Nexium to a patient for whom Plaintiff paid medical benefits would not have done so.

Plaintiff does allege that it relied upon misleading representations "for the purpose of . . . paying claims for Nexium." Complaint ¶ 61. But that bare allegation cannot overcome Plaintiff's failure to identify a single such representation upon which anyone affiliated with Plaintiff relied in making any decision involving Nexium. Plaintiff's allegation of reliance, unsupported by any factual allegations of misrepresentations, thus cannot compensate for its failure to allege the essential facts to establish causation.

In sum, Plaintiff has failed to allege that it made any purchasing decision as a result of any misrepresentation by AstraZeneca. Plaintiff thus has failed to allege causation, and its claim should be dismissed for this reason as well.

B. Plaintiff Fails to State a Claim for Violation of the Consumer Protection Statutes of the 50 States.

Plaintiff's "[a]lternative[]" claim for violation of the deceptive practices and consumer fraud acts of the fifty states (Complaint ¶ 65), should be dismissed for the additional reason that the only relevant issue at this stage is whether Plaintiff states a

claim under the DCFA; with respect to other potential class members and other state laws, Plaintiff's claim is over inclusive and irrelevant. *See, e.g., Fitzgerald v. Chrysler Corp.*, 1996 WL 473456, at *7 (N.D. Ill. 1996) (finding plaintiffs' "shotgun" method of pleading violations of the consumer fraud statutes of the fifty states and the District of Columbia "overinclusive" and addressing only the law of the forum state on a motion to dismiss), *aff'd* 116 F.3d 225 (7th Cir. 1997).

Moreover, with the arguable exception of Pennsylvania, Plaintiff has failed to alleged that it has standing to maintain a claim under the laws of any other state. It alleges only that it "has paid, in Delaware and elsewhere, for some or all of the purchase price of Nexium." Complaint ¶ 13. Plaintiff does allege that it is a Pennsylvania organization and that some of its participants and beneficiaries "live . . . in Pennsylvania," *id.*, but even assuming this allegation gave Plaintiff standing to bring a claim under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), any such claim is based on the same allegations as Plaintiff's DCFA and other claims (*see* Complaint ¶ 64) and suffers from the same fatal deficiencies. *See supra* Parts I, II.A.2.

In addition, a UTPCPL claim requires a plaintiff to prove "specific reliance on some conduct or representation by the defendant that caused him to incur the loss in question." *Sexton v. PNC Bank*, 792 A.2d 602, 607 (Pa. 2002). Plaintiff has not identified any conduct or representation by Defendants upon which Plaintiff has alleged that anyone affiliated with it relied; its general allegation that AstraZeneca "knew" that its representations "were being relied upon by physicians, Plaintiff and the Class" (Complaint ¶ 61) does not cure this defect, let alone satisfy the particularity requirement

of Rule 9(b). *See, e.g., Lum*, 361 F.3d at 225 (dismissing claims based on allegations of fraud where plaintiffs did not allege that the representations "were made to a named plaintiff, or that any particular individual entered into a financial transaction with the challenged term"). For each of these additional reasons, Plaintiff's second cause of action should be dismissed.

C. Plaintiff's Fraud and Negligent Misrepresentation Claims Should Be Dismissed for Failure to Allege Justifiable Reliance or Causation.

Plaintiff's common law fraud and negligent misrepresentation claims also should be dismissed for failure to allege justifiable reliance or causation. A claim for fraud requires proof of:

> 1) a false representation, usually one of fact, made by the defendant; 2) the defendant's knowledge or belief that the representation was false, or was made with reckless indifference to the truth; 3) an intent to induce the plaintiff to act or to refrain from acting; 4) the plaintiff's action or inaction taken in justifiable reliance upon the representation; and 5) damage to the plaintiff as a result of such reliance.

Stephenson, 462 A.2d 1069, 1074 (Del. 1983). A claim for negligent misrepresentation requires proof of "(1) a pecuniary duty to provide accurate information, (2) the supplying of false information, (3) failure to exercise reasonable care in obtaining or communicating information, and (4) a pecuniary loss caused by justifiable reliance upon the false information." *Outdoor Technologies, Inc. v. Allfirst Financial, Inc.*, 2001 WL 541472, at * 5 (Del. Super. Ct. April 12, 2001) (citations omitted).

Plaintiff, however, has failed to plead any facts to support its allegation that it "relied upon the veracity of the Defendants' representations." Complaint ¶ 73. As explained above, Plaintiff has not alleged any facts to establish exposure to any alleged misrepresentation, let alone that anyone affiliated with Plaintiff took action (or refrained

from acting) in justifiable reliance on any representation or that it suffered any damage as a result of such reliance. Plaintiff thus also has not alleged that any misrepresentation or omission caused its alleged harm. *See* Parts II.A.2, II.B, *supra*. Accordingly, its fraud and negligent misrepresentation claims should be dismissed for these reasons as well.

D. Plaintiff Fails to State a Claim for Unjust Enrichment.

To state a cause of action for unjust enrichment, Plaintiff must allege "'(1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and the impoverishment, (4) the absence of justification, and (5) the absence of a remedy provided by law.'" *Total Care Physicians v. O'Hara*, 798 A.2d 1043, 1056 (Del. Super. Ct. 2001) (quoting *Jackson Nat'l Life Ins. Co. v. Kennedy*, 741 A.2d 377, 393 (Del. Ch. 1999)). Plaintiff's failure to allege the basic facts of causation also defeats its unjust enrichment claim, for without such allegations, the Complaint fails to allege circumstances to support any claim that it was inequitable for AstraZeneca to retain any funds that Plaintiff may have paid for Nexium. To take just one example, if a physician, in the exercise of his or her medical judgment, independently prescribed Nexium to a patient for whom Plaintiff paid medical benefits, then there can be nothing inequitable about that purchase of Nexium. Thus, for all of the reasons set forth above with respect Plaintiff's other claims, Plaintiff also has not adequately alleged the necessary facts to support an unjust enrichment claim. Accordingly, its unjust enrichment claim should be dismissed.

CONCLUSION

For all of the foregoing reasons, Plaintiff has failed to state any claim upon which relief can be granted, and its Complaint should be dismissed.

MORRIS, NICHOLS, ARSHT & TUNNELL

/s/ R. Judson Scaggs, Jr. (#2676)

Jack B. Blumenfeld (#1014)
R. Judson Scaggs, Jr. (#2676)
1201 North Market Street
P. O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
Attorneys for Defendants

OF COUNSEL:

SIDLEY AUSTIN BROWN & WOOD LLP
Peter I. Ostroff
Mark E. Haddad
Alycia A. Degen
555 West Fifth Street
Los Angeles, CA 90013
(213) 896-6000

March 31, 2005

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS was caused to be served this 31st day of March, 2005 upon the following by electronic filing:

Joseph A. Rosenthal (#234)
Jeffrey S. Goddess (#630)
ROSENTHAL, MONHAIT, GROSS & GODDESS
919 Market Street, Suite 1401
P. O. Box 1070
Wilmington, DE 19899-1070

/s/ R. Judson Scaggs, Jr. (#2676)